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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,884	07/30/2003	Kazunori Taniguchi	P/3541-39	7938

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,884

Applicant(s)

TANIGUCHI ET AL.

Examiner

Lindsey Bachman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 30 July 2003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Drawings

1. The drawings are objected to because element 20 in Figure 3 is labeled differently than Figure 4. Figure 4 refers to two frames, elements 20a and 20b, which is in agreement with the specification (page 10, line 9) while Figure 3 refers to both frames as 20a, which is not in agreement with the specification.

2. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is

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requested in correcting any errors of which applicant may become aware in the specification.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 5, 6, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

7. Claim 5 states that the extended portion has a slope inclined an axis of the sheath. This slope is not apparent from the drawings, nor is it described in the specification.

8. Claim 17 states that the attaching/detaching mechanism is switched between a position of being fixed to cover an outer periphery of the insertion section and a position of being shifted from the outer periphery of the insertion section. The meaning of these positions is not apparent from the specification and drawings.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 1, lines 7-9, describe an elongate member with distal and proximal ends, "and which is located in the distal end of the elongate member." This is unclear and further clarification is needed.

12. In Claim 3, there is insufficient antecedent basis for the term "elongate portion".

13. In Claim 7, there is insufficient antecedent basis for the terms "the sheath," "the insertion section," and "the biomedical tissue".

14. In Claim 8, there is insufficient antecedent basis for the terms "the insertion section," "the treatment section," and "the sheath."

15. In Claim 15, there is insufficient antecedent basis for the terms "first driving member," and "the sheath."

16. In Claim 16, there is insufficient antecedent basis for the term "first driving member."

17. In Claim 24, there is insufficient antecedent basis for the terms "the pivot."

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

19. Claims 1, 4-11, 23, 24, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hashiguchi (US Patent 6,063,103).

20. Regarding Claim 1, Hashiguchi discloses an endoscope forceps containing an end effector (4, 5) for use in a medical device, a support (8a), a base member (14) which pivotally supports the support, a sheath (7) is attached on the distal end of the pin (14), and an extended portion (8).

21. Regarding Claims 2-6, Hashiguchi'103 discloses an insertion section (2) containing an extended portion (8) covered with a long, tubular sheath (7) which is then covered with an electrically insulating tube (29) (see column 4, lines 46-63). Adjusting the location of the base member (14) with respect to the extended portion (8) can regulate the rotation of the support (see column 6, lines 33-49).

22. Regarding Claim 7, Hashiguchi'103 discloses that the extended portion (8) is reinforced with strength and designed to preventing bending from the application of operating forces (column 6, lines 27-31).

23. Regarding Claims 8-11, Hashiguchi'103 discloses that the insertion section (2) is connected to the treatment section (1) via support (8a) and several

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pins (12, 13 and 14). The sheath (7) has an inner tube (8) and an electrically insulating outer tube (29).

24. Regarding Claims 23 and 24, Hashiguchi'103 discloses that a support (8a) is also a pivot that supports the end effector (4, 5). He discloses that they pivot about the support (8a) with a pin (14) (See Hashiguchi'103 Figures 11-14)

25. Regarding Claim 32, Hashiguchi'103 discloses an insertion section (2) covered with a sheath (7), an treatment section (1) connected to the distal end of the insertion section (2), and an operation section (3) connected to the insertion section (2) and operated by an operator to generate a force in the treatment section (1). (See column 4, lines 46-63 and column 5, lines 42-50.)

26. Claims 12-14, 19-22, and 25-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Klieman, et al. (US Patent Number 5,827,323).

27. Klieman'323 discloses a surgical instrument comprising an end effector (40, 44), a support (distal end of driving member 34), a base member (48), a sheath (10), and an extended portion (26).

28. Regarding Claims 12-14, Klieman'323 discloses first and second driving members (32, 34) which are used for controlling "scissoring", or opening and closing the jaws (40, 44), and rotating the jaws. (See Figures 2B and 2C and column 3, lines 34-68).

29. Regarding Claims 19 and 25, Klieman'323 discloses an opening/closing section in the handle (2) in the proximal end of the instrument which is used to open and close the jaws (40, 44) by movement of the trigger lever (4) with respect to the stationary lever (5) which moves end effector (44) while end

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effector (40) remains stationary (see column 6, lines 18-31). (See column 1, lines 66-67 and column 3, lines 29-33 and 40-55.) Klieman'323 further discloses a rotation operation section (6) on the proximal end of the instrument to rotate the support (distal end of driving member 32) which is connected to the sheath (10). (See column 7, lines 1-8.)

30. Regarding Claims 20, 22, 26 and 28, Klieman'323 discloses a first transmitting member (32) which is dynamically connected to a jaw (44) in the distal and the opening/closing section (2) at element 20 in Figure 3A. (See Figure 2B.) Klieman'323 discloses a second transmitting member (34) connected to the rotation operation section (6) and support (distal end of driving rod 34). (See Figure 7A, where transmitting member 34 is connected to rotation operation section 6 and connected to the support which is located in sheath 10.)

31. Regarding Claims 21 and 27, Klieman'323 discloses first and second members (32, 34) which are dynamically connected via the base member (48). (See Figure 2A.)

32. Regarding Claim 29, Klieman'323 discloses a surgical instrument comprising an insertion section (10) with a notch (15) on its distal end, a treatment section (3), and an operation section (1) comprising a handle used to operate the treatment section (3).

33. Regarding Claim 30, Klieman'323 discloses that the treatment section can be rotated up to 110 degrees with respect to the insertion section (See column 3, lines 19-21.) Notch 15 is located within the 110 degree range. (See Figure 2A.)

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34. Regarding Claim 31, Klieman'323 discloses that his instrument is useful for electrocautery because it can be used to stop profuse bleeding during operations. The back of the handle (2) is connected to a plug (14) which receives an electrocautery cord. The plug (14) connects to an elongated member (32), which is electrically connected to the treatment section (40, 44). (See column 10, lines 35-49.) Klieman'323 discloses that the sheath is made of plastic (column 5, lines 62-63). It is commonly known that plastic is electrically insulating.

Claims 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyawaki, et al. (US Patent Number 6,066,151).

Miyawaki'151 discloses an attachment system (78) which is used to connect the sheath (31) to the extended portion (3).

35. Claims 15 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Miyawaki, et al. (US Patent Number 6,569,178).

36. Regarding Claims 15 and 16, Miyawaki'178 discloses a coagulation/cutting apparatus containing an end effector (305, 313), a support (286, 300), a base member (303), a elongated member (231), and an extended portion (203) (See Figures 22a and 28a). Miyawaki'178 discloses that the first driving member (271) which is connected to the end effector unit (203) are electrically connected and they aid in transmitting electricity to the end effector (305, 313) (column 22, lines 4-8). The sheath (231) has two sections: a stiff metallic core (231a) and an electrically insulating resin skin (231b) that covers the core. This electrically insulating resin is located on the external portion of the sheath (231b). It can be seen in Miyawaki'178's Figure 22a, that the sheath is

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placed over the extended portion (203); therefore, the electrically insulating portion of the sheath (231b) will cover the extended portion (203).

Claim Rejections - 35 USC § 103

37. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

38. **Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Klieman, et al. (US Patent Number 5,827,323) in view of Hashiguchi (US Patent 6,063,103).**

39. Klieman'323 teaches a surgical instrument with a pair of jaws on the end (see paragraph 27 above for further detail). Klieman'323 does not teach the use of a sliding member to open and close the jaws. Hashiguchi'103 teaches the use of a sliding member (7) that is slid with respect to the first driving member (8) to open and close jaws (4, 5). A connection member (located between pivot pins 12 and 13) with a proximal (near pivot pin 13) and distal (near pivot pin 12) end is connected to the distal end of the sliding member (7) and the proximal end of the first connection member (8). Hashiguchi'103 teaches this structure because it is "simple, excellent in strength and reliability, and low in cost," as well as easy to clean. (See column 7, lines 28-63.) Therefore, it would have been obvious to one skilled in the art at the time of the invention to use a sliding member to aid in opening and closing the jaws.

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Conclusion

40. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lmb

**GARY JACKSON
PRIMARY EXAMINER
GROUP 3300**

4/2/2006

Gary Jackson